

**REMARKS/ARGUMENTS**

**I. Status of the claims and other formalities**

In the response filed on July 30, 2008, Applicants amended the specification to provide a revised abstract. Submitted herewith as Appendix 1 is the revised abstract on a replacement sheet.

On page 2 of the Office Action, it is noted that the elected species is depicted in claim 79 wherein L is an anti-CD30 antibody and p is 4. According to the Action, art was identified that anticipates the elected species and the search was not extended to encompass any species other than the elected species. It appears, however, that the search was extended with respect to the value for the variable p. On page 5 of the action, the Patent Office alleges that the cited reference teaches an antibody drug conjugate having a p value of 8, not 4. Applicants respectfully request clarification. When the pending claims are found allowable over the prior art, Applicants request rejoinder of the withdrawn claims.

Upon entry of the present amendment, claims 1, 7, 9, 17-30, 44-46, 48, 49, 52, 54, 56, 59, 77, 79, 100, 104, 111, 119, 121, 122 and 124-164 are pending in the present application. With this response, claims 1, 7, 9, 17-20, 44, 54, 77, 79, 111, 122 and 128-130 are amended and claims 133 to 164 are added. Claims 2-6, 8, 10-16, 31-43, 47, 50-51, 53, 55, 57-58, 60-76, 78, 80-99, 101-103, 105-110, 112-118, 120, and 123 have been canceled. New claims 133, 136-149, 151, 153-156, and 160-163, read on the elected species.

Applicants have amended the claims solely to expedite prosecution of important subject matter and to correct Markush language, typographical errors and to maintain antecedent basis. The amendments are made without prejudice or disclaimer. No new matter has been added by this amendment. Specifically support for the amendment to claim 19 can be found throughout the specification and claims as filed, for example, page 111, lines 27-34 and page 112, lines 1-26. Support for the new claims can be found throughout the specification and the original claims as filed, for example, page 55, lines 10-21, page 82, lines 3-19, page 111, lines 27-34, page 112, lines 1-26, page 115, lines 7-13, and pages 148-154.

Any amendment or cancellation of the claims is without prejudice to future prosecution. Applicants reserve the right to pursue any originally-claimed subject matter in continuing applications. Entry of this amendment is respectfully urged.

Applicants note that on pages 2 and 3 of the Office Action mailed March 20, 2009, the Patent Office states claims 19, 22-26, 28, 29, 44-46, 48, 49, 52, 59, 100, 104, 122 and 129 are withdrawn. Applicants believe, however, that claim 19 is listed in error as it reads on the elected species. Claims 30, 56, and 77 should be added to the list of withdrawn claims as they were withdrawn in the Office Action mailed April 29, 2008.

Applicants also gratefully acknowledge withdrawal of the 35 U.S.C. §112 and §102 rejections from the previous Office Action.

The Examiner's rejections are addressed in the order in which they were presented in the Office Action mailed March 20, 2009.

**II. Rejection of claims 1, 7, 9, 17, 18, 20, 21, 27, 30, 54, 56, 63, 66, 77, 79, 111, 119, 121, 124-128 under 35 U.S.C. § 102(a) as being anticipated by Toki et al. (2004)**

On page 4 of the Office Action of March 20, 2009, the Examiner rejected claims 1, 7, 9, 17, 18, 20, 21, 27, 30, 54, 56, 63, 66, 77, 79, 111, 119, 121, and 124-128 under 35 U.S.C. § 102(a) as allegedly anticipated by an oral presentation made by Brian Toki ("the Toki presentation") at the 23<sup>rd</sup> ACS National Meeting in Orlando Florida on April 7-11, 2002. The title of the talk was "Cures and regression of established tumor xenografts with monoclonal antibody auristatin E". According to the Office Action :

"Based on the structure for the antibody-drug conjugate with doxorubicin and the compound names cBR96-phelys-MMAE, cAC10-phelys-MMAE, cBR96-valcit-MMAE, and cAC10-valcit-MMAE, the skilled artisan could readily envisage the antibody-drug conjugates of the instant claim" (Office Action at page 5).

Applicants disagree with the Patent Office's allegation that the information disclosed in the Toki. presentation anticipates the claims of the instant application. In order to expedite prosecution, however, Applicants are providing a declaration to remove the Toki presentation as alleged prior art under 35 U.S.C. 102(a). The disclosure of Applicants own work within the year before the application filing date cannot be used against them under 35 U.S.C. 102(a). Applicants herein provide a declaration in Appendix 2 stating that Peter Senter, Brian Toki, and Svetlana Doronina are the sole co-inventors of the claimed subject matter and that to the extent the subject matter disclosed and claimed in the present application is disclosed in the Toki presentation, it is their own work, i.e., they are the sole co-inventors of said subject matter. The Toki presentation was made within one year of the priority filing date of the present application. Accordingly, Applicants respectfully request that the rejection be withdrawn.

### **III. Provisional Obviousness-type Double Patenting Rejection.**

Claims 1, 7, 9, 17, 18, 20, 21, 27, 29, 30, 54, 63, 66, 77, 79, 111, 119, 121, 124-128 and 130-132 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-36 and 40-89 of co-pending U.S. Patent Application No. 11/833,959. In addition, claims 1, 7, 9, 17, 18, 20, 21, 27, 29, 30, 54, 56, 63, 66, 77, 79, 111, 119, 121, 124-128 and 130-132 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-19 of co-pending U.S. Patent Application No. 12/016,978 in view of Dubowchik *et al. Biorg. Med. Chem. Lett.* 1998, 8: 3347-52 and Blatter *et al.* U.S. Patent No. 4,764,368. Without acquiescing to the propriety of these rejections, Applicants request that matter be held in abeyance until allowable subject matter is found.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Mark H. Hopkins, Ph.D.  
Reg. No. 44,775

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
M3H/slh  
02058003 v1